

Food and Drug Administration
Rockville MD 20857

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The Weinberg Group Inc.
Attention: Nicholas M. Fleischer, Ph.D.
1220 Nineteenth Street, N.W., Suite 300
Washington, DC 20036-2400

Docket No. 2004P-0153/CP1

Dear Dr. Fleischer:

This is in response to your petition filed on March 30, 2004, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Oxycodone Hydrochloride Capsules, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg. The listed drug products to which you refer in your petition are Roxicodone™ (Oxycodone Hydrochloride) Tablets, 15 mg and 30 mg, manufactured by Roxane Laboratories, Inc.

Your request involves changes in strength and dosage form (i.e., from 15 mg and 30 mg tablets to 5 mg, 10 mg, 15 mg, 20 mg and 30 mg capsules) from that of the listed drug products. The changes that you request are the type of changes that are authorized under Section 505(j)(2)(C) of the Act.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Section 505(j)(2)(C)(i) and (ii) of the Act, such a petition will be approved unless the Agency finds that investigations must be conducted to show the safety and effectiveness of the proposed drug products, or of any of the active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug products; or that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

The Pediatric Research Equity Act (PREA) provides that a person who submits an application or supplement under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration shall submit assessments adequate to assess safety and effectiveness of the drug or biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration in each pediatric subpopulation in which the drug or biologic is safe and effective, unless the requirement is waived. 21 U.S.C. 355c. If a change proposed in a suitability petition triggers the need for pediatric clinical studies under PREA and those studies are not waived, the proposed product will not be eligible to be approved in an ANDA and the suitability petition must be denied.

Because you are seeking a change in dosage form, this proposed drug product triggers PREA. The Agency has determined that under PREA pediatric clinical trials are required. The Agency

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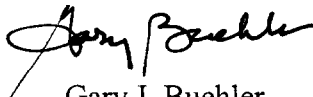
disagrees with your contention that the drug would not represent a meaningful therapeutic benefit over existing therapies, or that it is unlikely to be used in substantial numbers in the pediatric patient population and that therefore the PREA requirement for pediatric studies should be waived. It is important that effective analgesic products with appropriate labeling be made available for the pediatric patient population, since there is increasing evidence that inadequately treated pain in children can have significant long-term sequelae. Although pediatric patients may be more susceptible to the effects of opioids than adults, and respiratory depression may be particularly clinically important in this population, opioids continue to be used in this patient population. In arguing that the pediatric studies requirement for oxycodone hydrochloride should be waived, you list five therapies as evidence that multiple alternative therapies are approved for pediatric patients. However, not all of the therapies listed have comparable indications. Further, not all therapies are equally tolerated and rotation among several analgesics is often required in the course of pain management.

This petition is being denied because clinical trials are required under PREA for the approval of the requested changes to the drug product. The request for a waiver of the pediatric study requirement under PREA has been denied. Please contact the Division of Anesthetic, Critical Care, and Addiction Drug Products at 301-827-7410 if you wish to pursue approval of your product under Section 505(b) of the Act.

If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary Buehler", with a stylized flourish at the end.

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research